Defense Health Agency (DHA) Privacy and Civil Liberties Office, formerly known as the TRICARE Management Activity (TMA) Privacy and Civil Liberties Office's Submission of

DHA PRIVACY BOARD:

2013 FISCAL YEAR REPORT

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MESSAGE FROM THE DHA PRIVACY BOARD CHAIR

I am pleased to present the Fiscal Year 2013 (FY13) TMA Privacy Board Annual Report. With the stand-up of the Defense Health Agency (DHA) on October 1, 2013, the Board is currently referred to as the DHA Privacy Board. However, to the extent that this report refers to prior activities and accomplishments in FY13, this report makes reference to TMA. Future activities, moving into FY14, will address the DHA.

During FY13, new developments in the Military Health System (MHS) and in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's research provisions impacted and defined the ongoing activities of the Board. Reaffirmation received from DHA's Office of General Counsel (OGC) on the status of MHS as a single covered entity and as the owner of all data within the MHS led to many questions from the research community and other stakeholders about how HIPAA is implemented within the MHS. Also, advice received from OGC that TMA manages the MHS provider level data systems - Armed Forces Health Longitudinal Technology Application (AHLTA), Composite Health Care System (CHCS) and Essentris - raised the potential for an increase in requests for HIPAA Privacy Rule reviews by the Board. Fortunately, the Research Data Sharing Streamlining Initiative ("Streamlining Initiative"), previously approved and currently under development, will play a significant role in increasing the efficiency of HIPAA compliance reviews under TMA's (and now DHA's) responsibility. The Streamlining Initiative will ultimately delegate the reviews to Multi-Service Sites that are already reviewing research studies under the "Protection of Human Subjects and Adherence to Ethical Standards in Department of Defense Supported Research" (Department of Defense Instruction (DoDI) 3216.02) and will provide training and routine assessments to Institutional Review Boards (IRBs) and/or Privacy Boards within these Multi-Service Sites to ensure HIPAA compliance and protection of the MHS beneficiaries' data.

In addition, the HIPAA Omnibus Final Rule, released in January 2013, permits the use of a single compound Authorization for conditioned and unconditioned research activities and the use and disclosure of Protected Health Information (PHI) for future research. These changes benefit researchers by easing HIPAA compliance requirements and eliminating confusion with the Federal Framework for the Protection of Human Subjects (45 CFR 46), otherwise known as the "Common Rule" and implemented within the MHS through DoDI 3216.02. During FY13, the TMA Privacy Board worked to ensure the adoption of these changes within the MHS.

Although the previous report was based upon Calendar Year 2012 (CY12), this year's report presents the achievements of the Board during Fiscal Year 2013 (FY13), explains the success of the Board in meeting its metrics, and forecasts the direction of the Board in the upcoming year. It also explains the potential impact of the Streamlining Initiative and summarizes the changes in the research provisions resulting from the HIPAA Omnibus Final Rule.

MESSAGE FROM THE DHA PRIVACY BOARD CHAIR

In conclusion, I believe this past FY13 reflects the expanding significance of the Board as a great resource to the research community for HIPAA expertise in the changing MHS environment and as an advocate within the MHS for beneficial changes permitted under HIPAA.

Linda Thomas
Chief, DHA Privacy and Civil Liberties Office
Chair, DHA Privacy Board

Executive Summary

The TMA Privacy and Civil Liberties Office (TMA Privacy Office) commenced the operations of the TMA Privacy Board on August 25, 2009. Since its establishment, the Board has greatly improved the process for ensuring compliance with the requirements of the HIPAA Privacy Rule and the Department of Defense (DoD) Health Information Privacy Regulation (DoD 6025.18-R), while helping to clarify the complex intersection of the HIPAA Privacy Rule and the Common Rule. In addition, the Board has begun to consider privacy within the general context of contemporary privacy and research issues by including discussion at quarterly meetings on current topics. This thought provoking discussion complements and advances the Board's initial mission of enhancing compliance through process improvements, education and outreach efforts. The Board's growing knowledge of privacy and research related issues also helps in serving as a resource for the research community on HIPAA-related research topics and data sharing concerns.

This report highlights the major accomplishments of the TMA Privacy Board during FY13. There were three new significant developments that required the Board to adjust some of its processes: 1) A careful study of the streamlining possibilities in viewing the MHS as a HIPAA single covered entity; 2) Clarifying advice received regarding information systems owned by the MHS; and, 3) The release of the HIPAA Omnibus Final Rule implementing both the statutory amendments to HIPAA in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and the Genetic Information Non-Discrimination Act (GINA) and other modifications under the authority of the Department of Health and Human Services, Office of Civil Rights (DHHS/OCR). The new HIPAA Omnibus Final Rule, as well as recent developments within the MHS, motivated the development of a new DoDI 6025.18, currently pending review and coordination, that will ultimately replace the DoD 6025.18-R. In addition to the major accomplishments, this report provides an overview of the new DHA's possible impact on the Board and HIPAA Privacy Rule reviews, including the fortunate timing and relevance of the Streamlining Initiative, and a summary of the HIPAA Omnibus Final Rule's revisions to the research provisions that are being implemented within the MHS. The report concludes with the Board's vision for FY14.

TMA Privacy Board 2013 Highlighted Accomplishments
Board Operations and Process Improvements

1. **Successfully completed reviews of 31 submissions requesting TMA managed data and protected the privacy of that data totaling records for up to 5 million beneficiaries in strict adherence to the HIPAA Privacy Rule standards (See Figure 1 on page 7 and Figure 2 on page 8)**

2. **Served 18 different healthcare and research related Centers/Institutions with HIPAA compliance reviews for the Army, Navy, Air Force, Multi-Service Sites, and a civilian medical research center (See Figure 3 on page 9)**

3. **Achieved 100% percent compliance with review period mandates in FY13, resulting in an average completion of reviews within two days from the date of "perfection" (date of perfection is the date that all information necessary to review the application has been submitted) (See Figure 4 on page 10)**

4. **Revised the standardized, fillable PDF templates for the TMA Privacy Board to reflect that MHS is a single covered entity and owner of all MHS data**

5. **Updated the narrative content of the TMA Privacy Board webpage on the TMA Privacy Office website to reflect the stand-up of the DHA and explain its impact on the Board, and the acceptance of the new HIPAA Omnibus Rule on HIPAA research provisions**

6. **Successfully advanced the work of the Board through scheduled quarterly meetings and ramped up the agenda to include current topics to establish a platform for discussion and new perspectives from Board members, who are experts in privacy and research, to guide the TMA Privacy Board and enhance the mission of the TMA Privacy Board**

TMA Privacy Board 2013 Highlighted Accomplishments Research Community Outreach Efforts

1. **Successfully negotiated the completion of templates and developed a draft Memorandum of Agreement (MOA) for the pilot phase of the Streamlining Initiative at Walter Reed National Military Medical Center (WRNMMC), which is expected to impact approximately 1,100 MHS HIPAA Privacy Rule reviews and more than 10,000 MHS HIPAA Privacy Rule reviews after full rollout**

2. **Increased the protection of MHS data through detailed analysis of factual scenarios and clear guidance provided by TMA Privacy Board support staff, who have in-depth knowledge of HIPAA and the Common Rule to stakeholders in the researcher community, including researchers, IRBs and Human Research Protection Programs (HRPP)**

3. **Contributed to the dialogue and knowledge of HIPAA within sectors of the MHS outside of the research community by responding to issues about HIPAA related to their work-stream**

4. **Obtained approval from the Deputy Director of TMA to implement streamlining changes permitted in the new HIPAA Omnibus Final Rule pertaining to compound HIPAA Authorizations and the use of data for future research when permitted by the research subject in a HIPAA Authorization**

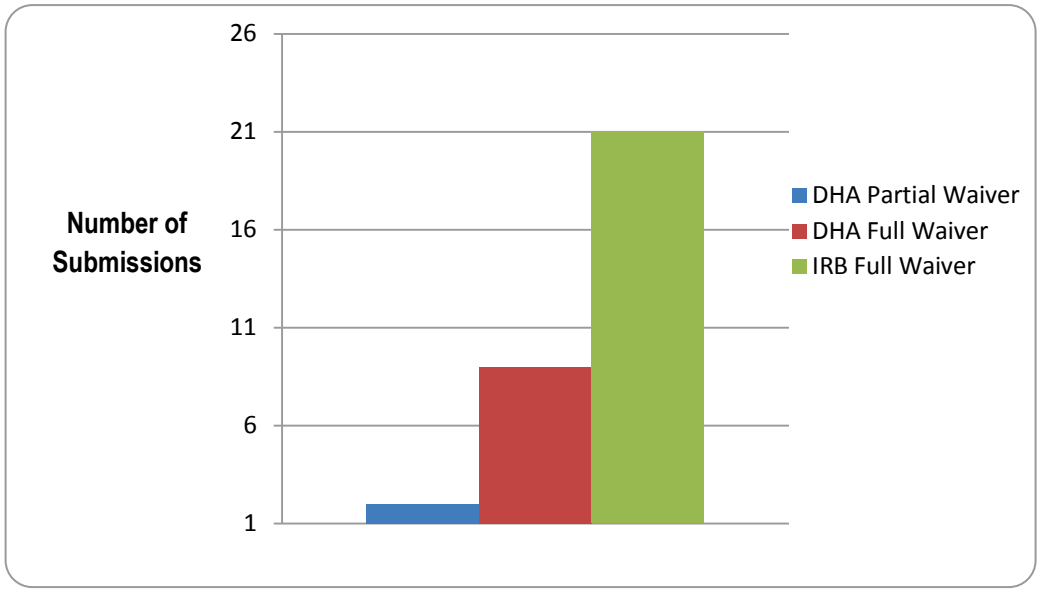
5. **Enhanced the understanding of the impact of the HIPAA Omnibus Final Rule by presenting to the DHA Privacy Office's Health Information Privacy and Security Compliance Committee (HIPSCC) on the new changes to the HIPAA Privacy and Security Rules and the implementation plan to ensure compliance with the new regulation**

Description of the TMA Privacy Board's FY13 Major Accomplishments

1. Successfully completed reviews of 31 submissions requesting TMA managed data and protected the privacy of that data totaling records for up to 5 million beneficiaries in strict adherence to the HIPAA Privacy Rule standards

By offering researchers the service of HIPAA Privacy Rule reviews, the TMA Privacy Board ensured HIPAA compliance through its templates that: 1) Ask for documentation necessary to meet HIPAA requirements; and 2) Guide the reviewers in making the proper findings to meet HIPAA standards. Thus, the reviews enhance the privacy protections of the individuals in the MHS whose PHI is part of a research request. The process used by the TMA Privacy Board for reviewing research related requests is set forth in Appendix C. For FY13, these reviews and approvals included submissions of 31 applications to the TMA Privacy Board for waivers of HIPAA Authorization, including one DHA partial waiver; eight DHA full waivers; and 21 IRB full waivers. The Board did not review any HIPAA Authorizations.

Figure 1: Frequency of Types of Submissions



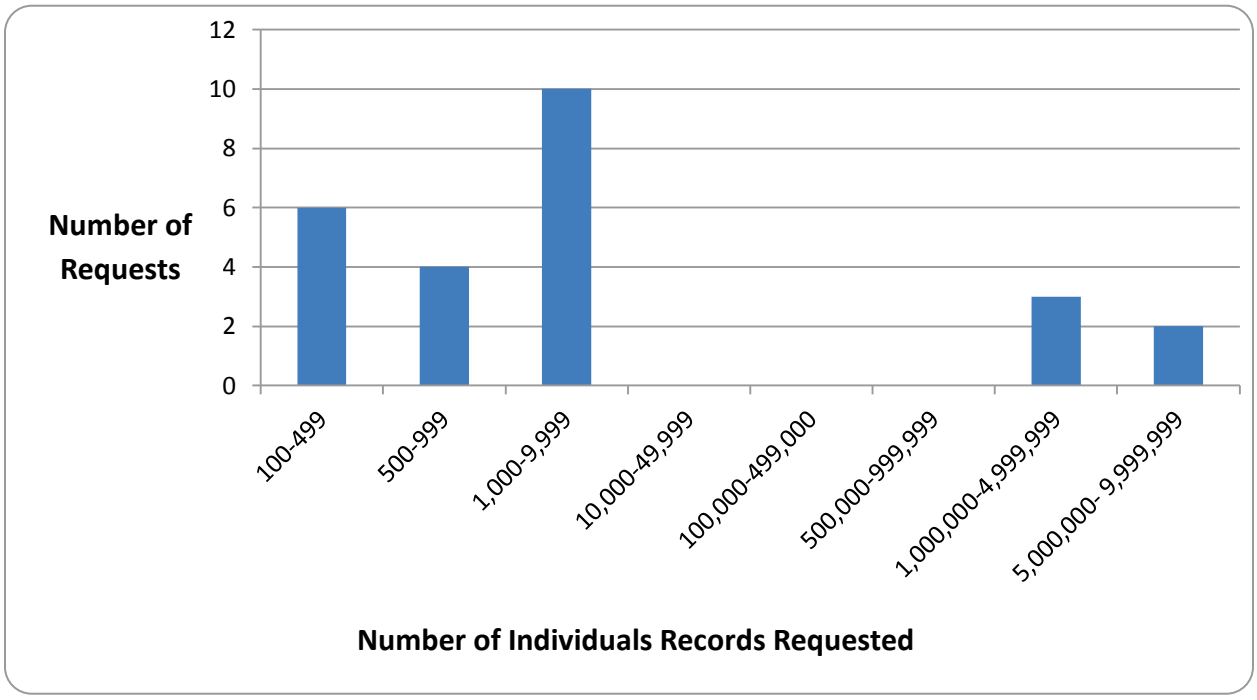
DHA Partial Waiver: Authorizes the use of PHI without Authorizations from the participants for part of the research project and ends when the need for PHI without Authorizations has ended.

DHA Full Waiver: Authorizes the use of PHI with Authorizations from the participants for the entire research project, so as the purpose and data requested remain the same

IRB Waiver: Administrative reviews that ensure that all required regulatory elements are included in the waiver documentation presented by a MHS IRB

During FY13, the number of individuals whose PHI was requested for a single research project ranged from 200 individuals to 5 million individuals. This wide range in the number of individuals was due in part to how the researchers identified the number of individuals whose information they expected to access. For example, some researchers provided the actual number of research subjects whose PHI they expected to collect, while others provided the approximate number of individuals whose PHI is contained in the MHS data systems they intended to access to locate their research subjects. The TMA Privacy Board's efforts to ensure HIPAA Privacy Rule and DoD 6025.18-R compliance protected the data for all of these individuals.

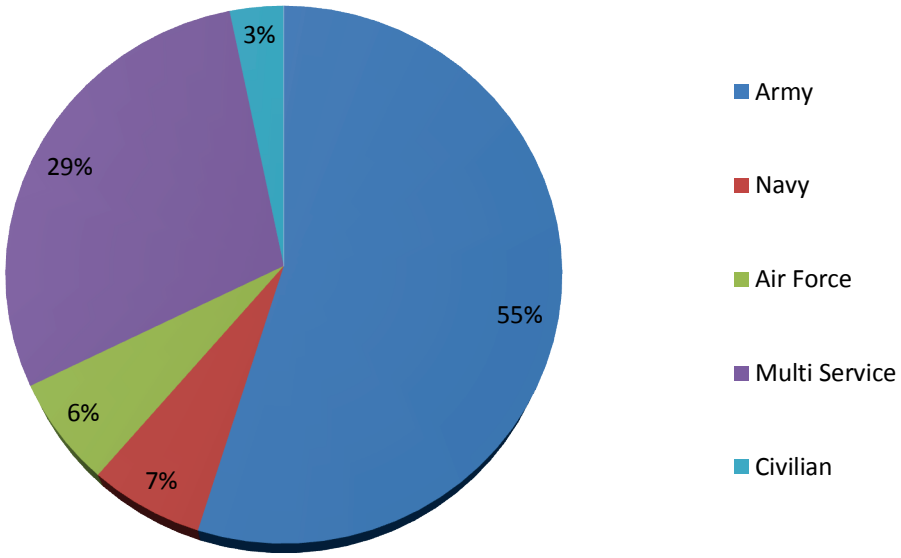
Figure 2: Frequency of Number of Individuals Records Requested in FY13



2. Served 18 different healthcare and research related Centers/Institutions with HIPAA compliance reviews for the Army, Navy, Air Force, Multi-Service Sites, and a civilian medical research center

During FY13, the TMA Privacy Board served 18 different research Centers/Institutions through its HIPAA compliance reviews for the Army, Navy, and Air Force, as well as in Multi-Service and civilian sites. (See Appendix B for listing of specific research Centers/Institutions.) By conducting efficient and compliant HIPAA Privacy Rule reviews, the TMA Privacy Board supported these Centers/Institutions by offering reviews for waivers of HIPAA Authorizations that they may not otherwise have been able to obtain. Also, the TMA Privacy Board helped these Centers/Institutions meet the compliance requirements necessary for them to receive MHS data.

Figure 3: Types of Centers/Institutions Served by the TMA Privacy Board in FY13



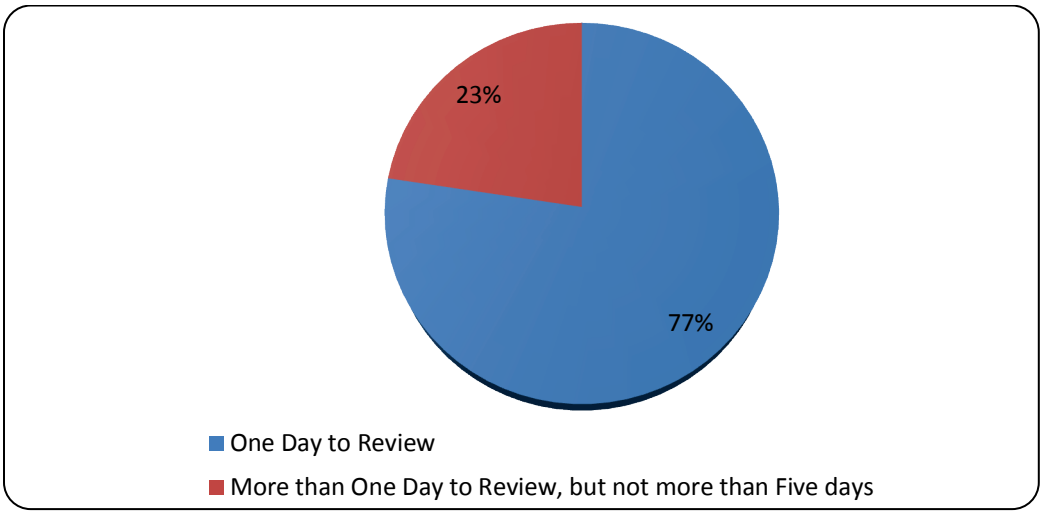
*Multi-Service includes programs that serve more than one branch. A complete listing of the Centers/Institutions can be found in Appendix B.

3. Achieved 100% percent compliance with review period mandates in FY13, resulting in an average completion of reviews within two days from the date of perfection

The TMA Privacy Board's Standard Operating Procedures (SOP) provide Board members with five days to respond to the principal investigator (PI) and/or government sponsor (Sponsor) named in a submission with the results of the review or follow-up questions, as necessary. This metric for review time counts the number of days from the day after the review is "perfected", which is when all of the necessary documentation for review has been submitted. Using the date of perfection and date of approval, the average time for review of an application for a waiver of HIPAA Authorization was two days for FY13. With one exception, reviews were completed in only one day once the submission was perfected by the PIs and Sponsors. The exception required additional days for review in order to answer the issue raised by the submission regarding whether the request for data included psychotherapy notes that may only be obtained for research with an individual HIPAA Authorization. Due to time limits imposed on research projects that are associated with funding, researchers appreciate quick and timely reviews. The support staff works with the researchers and reviewers to assist in any delays due to incomplete submissions or the need for understanding by the reviewers or researchers. The researchers have shown their appreciation of the Board's efforts with comments such as those noted above received by the support staff.

> ***"Thank you. You have been very helpful throughout this process,"***
>
> *- Principal Investigator, Uniformed Services University of the Health Sciences (USUHS)*
>
> ***"Thank you very much for your prompt response! I appreciate the additional information and guidance."***
>
> *-Sr. Research Reviewer, Army*

Figure 4: 100% Compliance with Review Times in FY13



4. ***Revised the standardized, fillable PDF templates for the TMA Privacy Board to reflect that MHS is a single covered entity and owner of all MHS data and required to ensure compliance with the requirements of the HIPAA Privacy Rule and DoD 6025.18-R***

During CY12, the TMA Privacy Board converted the seven TMA Privacy Board templates from Microsoft Word documents to fillable PDFs, and conducted 508 compliance reviews of each template in accordance with the federal regulation requiring accessible public documents for people with disabilities. Since the Streamlining Initiative led to the affirmation of the MHS as a single covered entity, with all data being owned by MHS, the Board updated the Board templates during FY13 to reflect the status of the MHS as a single HIPAA covered entity. The previous watermarked templates on the TMA Privacy Board webpage will be replaced with updated templates reflecting both the MHS as the owner of the data and the DHA as the new entity and name of the Board moving forward.

5. ***Updated the narrative content of the TMA Privacy Board webpage on the TMA Privacy Office website to reflect the stand-up of the DHA and explain its impact on the Board, and the acceptance of the new HIPAA Omnibus Rule on HIPAA research provisions***

The restructuring and realignment associated with the establishment of the DHA required the Board to update the recently launched TMA Privacy Board webpage. In addition, with the HIPAA Omnibus Rule's changes to the research provisions in the HIPAA Privacy Rule, the Board used the TMA Privacy Board webpage as the most efficient way to update the MHS research community of the new guidance and updated processes. The Board added to the webpage a separate tab announcing the MHS adoption of: 1) the HIPAA Omnibus Rule's research provisions allowing a single compound HIPAA Authorization for conditioned and unconditioned HIPAA Authorizations; and, 2) guidance permitting use of MHS data for future research when clearly outlined in a HIPAA Authorization.

6. ***Successfully advanced the work of the Board through scheduled quarterly meetings and ramped up the agenda to include current topics to establish a platform for discussion and new perspectives from Board members, who are experts in privacy and research, to guide the TMA Privacy Board and enhance the mission of the TMA Privacy Board***

In an effort to gain from the benefits provided by the expertise of the Board's members, the agenda at the quarterly Board meetings now includes a current topics section that raises the latest issues in privacy and research, such as how to handle Big Data and the new revelations about the ability to identify individuals from data previously considered de-identified. By adding this section to the agenda, the Board members contribute to a robust discussion on new and emerging areas to which they have specialized knowledge based on their backgrounds and experiences. Their thoughts and insight enable a new view of how to direct the efforts of the TMA Privacy Board and contribute to new strategic considerations for the TMA Privacy Office in order to protect MHS data used in research projects. For example, a Board member shared an article about the health information that States sell for profit. She stated that in her work at the Centers for Disease Control (CDC), they consider other data available before disclosing requested data to determine whether it may be re-identified. Although the OCR guidelines on de-identification do not require consideration of all possibilities for re-identification, the TMA Privacy Board's awareness of Big Data's availability improves the ability to protect MHS data before release, especially with extra-sensitive data such as genetic information.

7. ***Successfully negotiated the completion of templates and developed a draft Memorandum of* Agreement *(MOA) for the pilot phase of the Streamlining Initiative at Walter Reed National Military Medical Center (WRNMMC), which is expected to impact approximately 1,100 MHS HIPAA Privacy Rule reviews and more than 10,000 MHS HIPAA Privacy Rule reviews after full rollout***

As part of the pilot project for the Streamlining Initiative, the TMA Privacy Board worked with WRNMMC through meetings and correspondence to: 1) develop uniform templates for IRBs and/or HIPAA Privacy Boards within WRNMMC to use for the HIPAA Privacy Rule compliance reviews; 2) revise the WRNMCC Common Rule templates to incorporate HIPAA compliant reviews and appropriate HIPAA language; 3) create a Data Determination Guide to assist WRNMMC in properly categorizing and documenting the type of research related data requested; and, 4) develop a draft MOA incorporating the terms and conditions for delegating HIPAA Privacy reviews of research studies to the IRBs/HIPAA Privacy Boards within WRNMMC and the requirements necessary to achieve the objectives of protecting the privacy of MHS patients' PHI and improving the efficiency of review. The Board also assisted in the development of an overarching Data Sharing Agreement Application (DSAA) for two foundations, Geneva and Henry Jackson, which will allow researchers working for the foundations to receive MHS data without executing separate Data Sharing Agreement Applications (DSAAs). The decrease in the number of DSAAs reduces the processing burden and time consumed by the researchers and TMA Privacy Office data sharing analysts.

8. ***Increased the protection of MHS data through detailed analysis of factual scenarios and clear guidance provided by TMA Privacy Board support staff, who have in-depth knowledge of HIPAA and the Common Rule, to stakeholders in the researcher community, including researchers, IRBs and Human Research Protection Programs (HRPP)***

During CY 12, the TMA Privacy Board reported that support staff often received questions, by email and phone, from members of the research community regarding the review process and how to apply HIPAA to their work activities. These inquiries continued and increased in FY13, in large part due to both the organizational changes in the MHS and the increased awareness and understanding of the MHS status as a single covered entity. For example, a Human Research Protection Compliance Administrator asked several questions, including:

"If the MHS is a single covered entity, is any use of PHI maintained in Army medical records by any investigator associated with an Army Military Treatment Facility (MTF) a 'use,' or if not, at what point does it become a 'disclosure'?" and

"If use and disclosure are associated with a specific MTF (rather than the MHS), may we define in our HRPP (which has oversight of all HSR at the 10 facilities mentioned) that 'use' occurs when access to PHI is by any investigator who falls under the oversight of the DDEAMC HRPP to records maintained at any of the 10 health care facilities? If not, at what point does access to PHI become a 'disclosure'?"

The Board provided thoughtful and detailed response to these complex regulatory questions that assisted the research community in understanding the HIPAA Privacy Rule and its application to the MHS as a single covered entity.

9. ***Contributed to the dialogue and knowledge of HIPAA within sectors of the MHS outside of the research community by responding to issues about HIPAA related to their work-stream***

Due to the growing awareness of the TMA Privacy Board's subject matter expertise in HIPAA, the support staff also received questions related to HIPAA raised by members of the MHS not directly involved in research. The support staff provided answers to these questions, and often the answers led to further questions on HIPAA by the same people, who now turn to the Board as an important resource for HIPAA expertise. For example, the Board was forwarded a question from a Naval Medical Center San Diego HIPAA Privacy Officer and member of the HIPSCC on how to apply HIPAA when health information is requested under the Freedom of Information Act (FOIA). The TMA Privacy Board quickly provided assistance with the TMA Privacy Office response by quoting the preamble to the HIPAA Privacy Rule's guidance in which the OCR discusses the interaction between the two statutes. This same committee member followed-up this question with another HIPAA issue related to the application of both DoDI 6490.08, "Command Notification Requirements to Dispel Stigma in Providing Mental Health Care to Service Members" of 17 A and DoD 6025.18-R. Similarly, the Board assisted in responding to questions received after the Health Information Privacy and Security Training.

10. ***Successfully advocated for and received approval from the Deputy Director of TMA to implement changes permitted in the new HIPAA Omnibus Final Rule pertaining to compound HIPAA Authorizations and the use of MHS data for future research when permitted by the research subject in a HIPAA authorization***

The new HIPAA Omnibus Rule allows for a single compound Authorization that includes both an Authorization for conditioned research activities and an Authorization for unconditioned research activities. In addition, the HIPAA Omnibus Final Rule now allows researchers to obtain a HIPAA Authorization for future research, so long as the Authorization reasonably informs the participant of the intent to use the PHI for future research. Both of these changes benefit researchers by unifying the requirements of the Common Rule and the HIPAA Privacy Rule. The TMA Privacy Board identified these changes as an opportunity to improve processes on the research side while continuing to protect participant data and worked to ensure that the MHS adopt as part of its standards the new compound HIPAA Authorization rule and the new guidance on allowing the use and disclosure of MHS data for future research projects.

11. Enhanced the understanding of the impact of the HIPAA Omnibus Rule by presenting to the HIPSCC on the new changes to the HIPAA Privacy and Security Rules and the implementation plan to ensure MHS compliance with the new regulation

In line with the Board's education and outreach efforts, the TMA Privacy Board Chair presented a detailed overview of the HIPAA Omnibus Final Rule and summarized the major changes made to the HIPAA Privacy and Security Rules. Impact papers and slides were also prepared, including proposed "To-Do" lists for both TMA and the Services with respect to what actions should be taken to implement the regulatory changes. The overview included a highlight of the changes that impact the MHS including breach response, business associate status, the civil penalties increase, updates to Notice of Privacy Practices (NoPP), electronic access to PHI and medical records, restrictions on disclosures – self-paid care as well as the previously discussed research authorization changes, genetic information, proof of immunization in schools and PHI status and disclosure after death.

The TMA proposed implementation To-Do list was outlined, detailing the necessary steps identified to comply with the new regulation. The To-Do lists included requirements to update existing policy and guidance on breach response and new versions of the Personally Identifiable Information/Protected Health Information (PII/PHI) standard contract language and the standard business associate agreement (BAA) language as well as the drafting of DoD issuances on HHS breach compliance and revisions to DoD's implementation of the HIPAA Privacy Rule, DoD 6025.18-R. The To-Do list also included steps needed to identify contracts to be renewed, amended or entered into in order to maintain compliance, and to inform all contractors of the compliance dates and deadlines for amending contracts to comply with the Final HIPAA Omnibus Rule.

Additional discussion outlined specific processes that should be adhered to such as honoring, and reviewing existing technical capabilities to respond to, beneficiary requests for electronic copies of their electronic PHI, including beneficiary designations of a third party to receive the copies and honoring and reviewing existing technical capabilities to respond to, beneficiary requests to restrict disclosures about self-paid health care services to health plans.

Among other things, the implementation To-Do list described the required changes needed to revise the MHS Notice of Privacy Practices (NoPP) and the requirement for disseminating the revised NoPP so that it is available to all MHS beneficiaries via links in websites and mailings. The To-Do implementation plan further described the necessity of obtaining the appropriate leadership decision on changing human subject research authorizations as permitted by the HIPAA Omnibus Final Rule and to develop conforming authorization forms.

Finally, the presentation summarized the plan for conducting initial training/awareness activities by the September 23, 2013 compliance deadline.

DHA Privacy Board Trends

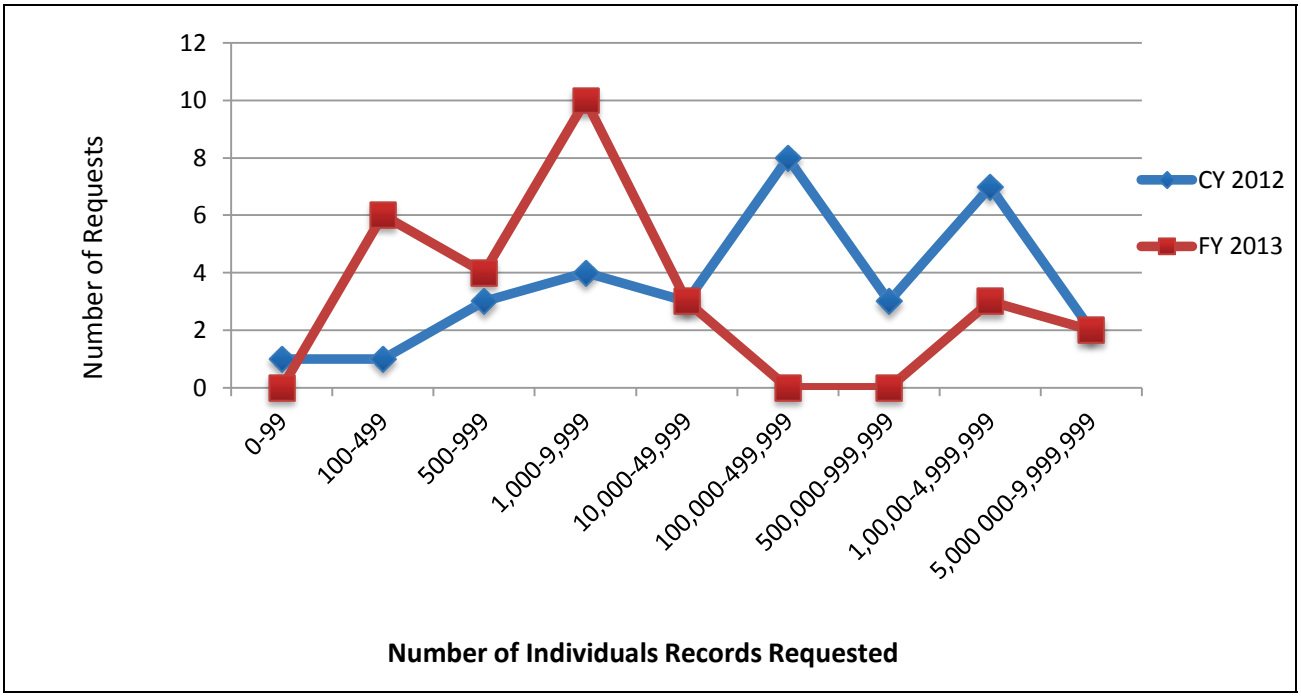
As the DHA Privacy Board develops and expands, the recordkeeping of important metrics will help to identify areas that need improvement as well as begin to track trends in data to better serve its customers.

This FY13 report transitions over from the calendar year approach, previously used during CY12 TMA Privacy Board Report. This FY13 report focuses on data from October 1, 2012 through September 30, 2013. The CY12 report focused on data from January 1, 2012 through December 31, 2012. The trend data below is slightly skewed as the reporting periods are not aligned; however, this year's trend data will present an overall picture of the direction the DHA Privacy Board is going and will continue to grow in future reporting periods.

1. ***The TMA Privacy Board tracks the number of participants whose records are being requested for the study***

During CY12 there was a larger range of the number of individuals whose records were requested as compared to FY13. This could be due to the types of studies that were submitted for the review and the number of records required for the studies. As the Board gathers more data over the years, there will be better data to assess the trends and impact on the number of records requested.

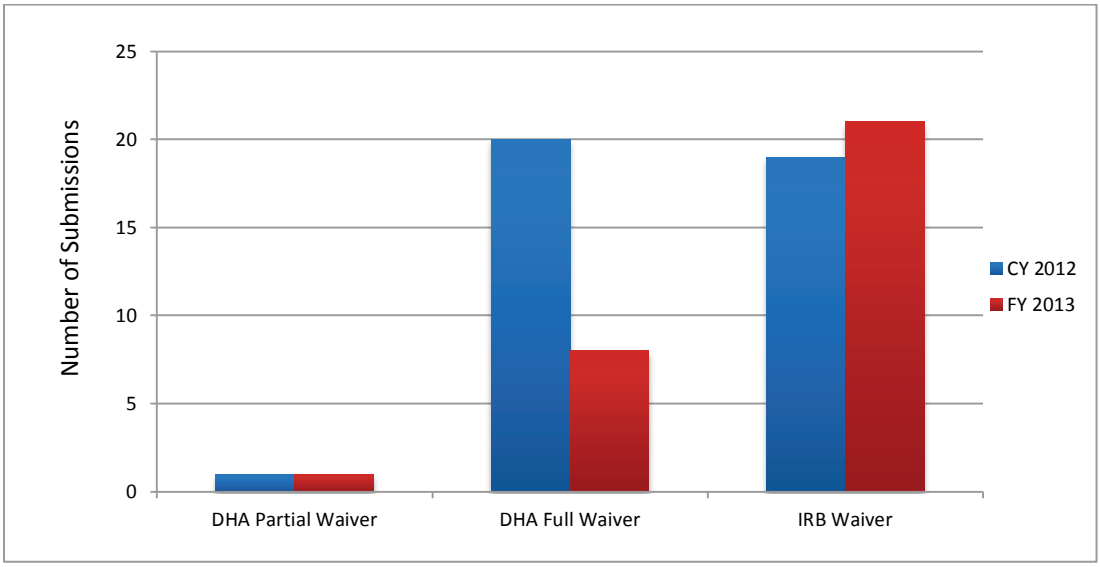
Figure 5: Trends in Frequency of Number of Individuals Records Requested



2. DHA Full Waivers and IRB Waivers are the most common types of submissions, with an increase in the number of IRB Waivers obtained in FY13, as more and more IRBs are educated on HIPAA compliance

Compared to CY12, there has been a decrease in the number of reviews for DHA full waivers of HIPAA Authorization conducted by the Board while the number of reviews for IRB waivers and reviews for DHA partial waivers remain relatively comparable. It is anticipated that as the Board continues various streamlining and outreach efforts, the review of IRB waivers submitted by Multi-Service Sites will decrease as those Centers/Institutions that enter into an agreement with the DHA will conduct their own reviews without the requirement of an administrative review by the DHA Privacy Board. However, it is expected that submissions for DHA partial and full waivers may experience a noticeable increase due to an increase in Centers/Institutions that fall under the purview of the DHA and a heightened awareness from DHA Privacy Board outreach efforts that research related studies involving PHI require HIPAA Privacy compliance review in addition to those requirements under the Common Rule.

Figure 6: Trends in Frequency of Types of Submissions

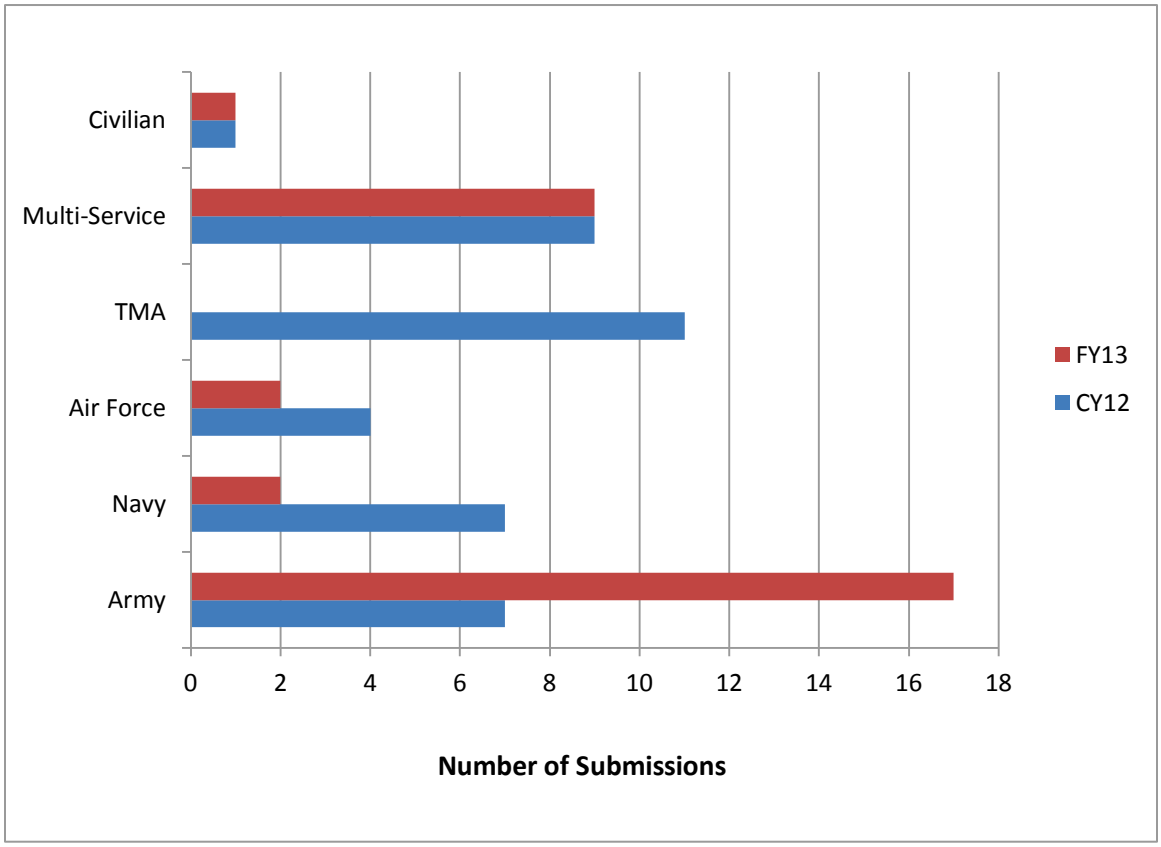


Note: Figure 1, page 7 provides a description of DHA Partial waiver, DHA Full Waiver and IRB Waiver

3. The types of organizations served by the TMA Privacy Board will change over time as streamlining efforts are implemented for HIPAA compliance

In FY13 the Army demonstrated the most significant increase in the number of submissions to the Board. Air Force, Multi-Service and Civilian Centers/Institutions number of submissions remained relatively similar for both CY12 and FY13. There was no TMA representation in submissions in FY13 as compared to CY12 where a significant number of submissions were from TMA. Although no impact can be measured for FY13, it is anticipated that the number of Multi-Service Sites may decrease once streamlining initiatives are fully implemented, permitting those sites who enter into agreements with DHA to conduct their own compliance reviews. However, it is also anticipated that the overall number of Centers/Institutions served could increase as more are placed under the purview of the DHA.

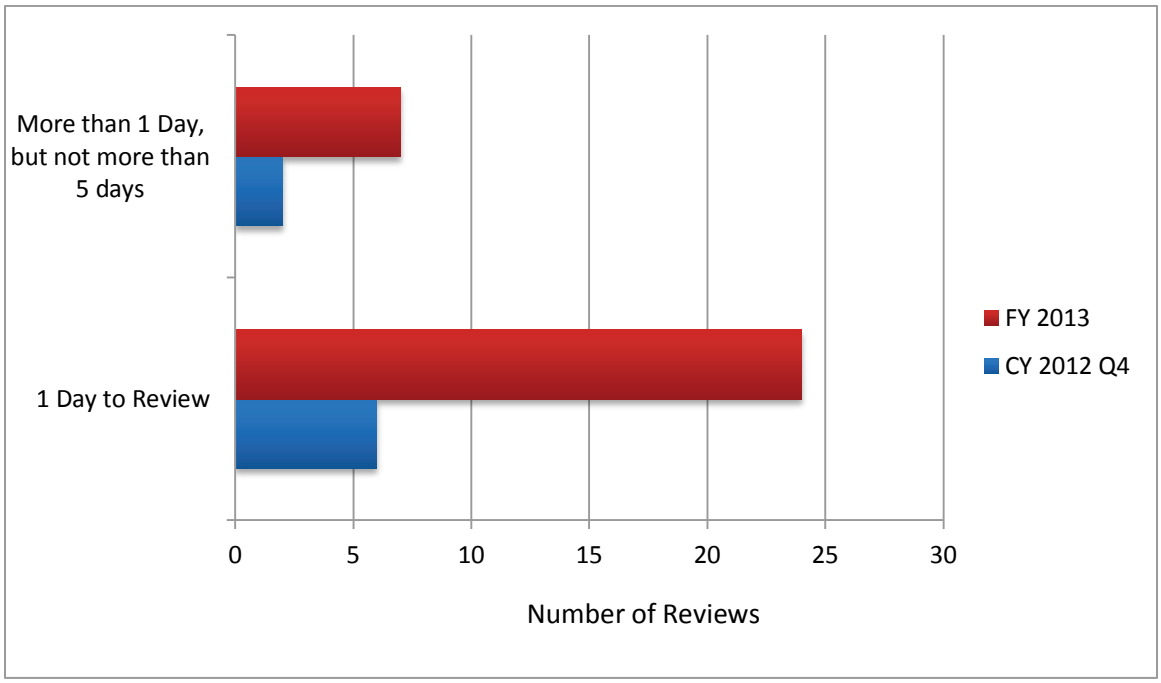
Figure 7: Trends in Types of Centers/Institutions Served by TMA Privacy Board



4. The TMA Privacy Board has enhanced its efficiency in conducting HIPAA compliance reviews

While there was limited data from 2012 with only the 4th Quarter of the CY12 representation being captured, there has been an increase in the number of reviews that have taken only one day to review. There were no reviews that took longer than five days to review. In order to provide a complete landscape of the trends for this metric, we will have to wait for the complete FY14 data, however it is anticipated that as the Board continues to improve their processes and procedures that there will continue to be increases in one day review turn-around times.

Figure 8: Trends of 100% Compliance with Review Times



The DHA Privacy Board Review Process

1. Determining the Data Type

Prior to review by the DHA Privacy Board, researchers must submit a Data Sharing Agreement Application (DSAA) to the DHA Privacy Office. The DHA Privacy Office then considers the type of information needed by the research project. The DHA Privacy Office categorizes a research project's informational needs into one of four types for compliance review: 1) De-identified data; 2) PII excluding PHI; 3) Limited data set (LDS); or 4) PHI greater than an LDS. An explanation of the four types of informational categories is available on the DHA Privacy Board section of the DHA Privacy Office website.

A research project that seeks PHI greater than an LDS is sent to the DHA Privacy Board for HIPAA Privacy Rule review and documentation. Once the DHA Privacy Board receives a research project submission seeking PHI greater than an LDS, the Board will reach out to the PI and Sponsor and begin the HIPAA Privacy Rule review process.

This process is briefly described below and illustrated in the flowchart entitled "DHA Privacy Board Review Process for Research Related Data Requests," attached in Appendix C.

2. Types of Privacy Board Reviews

In the initial email to the PIs and Sponsors regarding the need for documentation to demonstrate compliance with the HIPAA Privacy Rule and DoD 6025.18-R, the DHA Privacy Board outlines four possible types of submissions that the researchers may submit to meet the required standards, as appropriate. They include the following: 1) Required Representations for Research on Decedent's Information; 2) Required Representations for Review Preparatory to Research; 3) Research Authorization Review and sample HIPAA Authorization(s); and 4) Waiver of HIPAA Authorization or an Altered HIPAA Authorization from an IRB or HIPAA Privacy Board, including a DHA Privacy Board Application for a Waiver of Authorization or a request for the DHAA Privacy Board to conduct an Altered Authorization review.

When reviewing the above-referenced documents, the DHA Privacy Board will contact the PI and Sponsor to complete its review, as necessary. Once the DHA Privacy Board completes the HIPAA Privacy Rule review, the DHA Privacy Office continues processing the DSAA for additional compliance requirements.

Detailed information about the DHA Privacy Board reviews, including the required documentation, standards for review and the DHA Privacy Board HIPAA compliant templates, is outlined in the DHA Privacy Board SOPs, available on the DHA Privacy Board section of the DHA Privacy Office website.

HIPAA Omnibus Final Rule's Research Related Provisions

The new HIPAA Omnibus Rule, effective on September 23, 2013, makes changes that positively impact research by unifying some of the requirements for HIPAA Privacy Rule Authorization and Common Rule consent and review. Recall that researchers seeking to access and/or obtain the MHS data for research purposes must adhere to the separate and distinct requirements within both the Common Rule and the HIPAA Privacy Rule (See Appendix D for the difference between the Common Rule and the HIPAA Privacy Rule). The HIPAA Omnibus Rules changed the previous requirement for separate HIPAA Authorizations for the use of PHI for conditioned and unconditioned research activities to allow, in 45 CFR §164.508 (b)(3)(i), a single HIPAA Authorization for both conditioned and unconditioned research activities. In the case of a conditioned research activity, the covered entity conditions research-related treatment, such as a clinical trial, on obtaining a HIPAA Authorization from the individual to use and disclose PHI. In contrast, an unconditioned research activity does not require the covered entity to condition treatment on obtaining a HIPAA Authorization from the individual, for example, creating a data base or conducting future research with the individuals PHI.

The new HIPAA Omnibus Rule allows a compound Authorization for research that combines both conditioned and unconditioned research activities, provided that the single compound Authorization clearly differentiates between the two and allows the individual to indicate or check an opt-in box to the unconditioned research activities. For example, the covered entity may require the study participant to sign the Authorization to use and disclose PHI to receive research-related treatment, and the same Authorization may include a separate opt-in provision allowing the participant to, as an example, check yes or no as to whether the PHI collected may be used or disclosed for the creation of a research data base.

In addition, the new Omnibus Rule's guidance changed the previous requirement that a HIPAA Authorization's stated research purpose be study specific. Now, the guidance permits the required statement of research purpose to include the use and disclosure of PHI for future research studies. However, the HIPAA Authorization must include in the purpose an adequate description of the future uses and disclosures that would reasonably inform an individual that the PHI could be used or disclosed for future research.

As noted above in the Board accomplishments, The DHA Privacy Board worked to ensure that the MHS adopt as part of its standards the new compound HIPAA Authorization rule and the new guidance on allowing the use and disclosure of MHS data for future research projects. Approval was obtained from the Deputy Director of DHA to implement the aforementioned changes and efforts are underway to roll out that implementation within the MHS.

DHA and the Streamlining Initiative

The newly created DHA realigns the MHS by combining common clinical and business processes and standardizing specific shared services provided by all three branches of the military into one joint operation provided by one agency. The impact on the DHA Privacy Board is not fully known at this time; however, the Board will continue to provide its expertise and services to the research community through the HIPAA Privacy Rule compliance reviews and documentation, and through dialogue and communication with stakeholders. It is anticipated that the Board's role in providing HIPAA compliance reviews could expand, in terms of the number of reviews provided, as more Centers/Institutions are placed under the purview of the DHA.

With the potential increase in the number of data sharing requests due to the consolidation of business and clinical services under DHA, and the re-characterization of who manages various information systems within the MHS, the Research Data Sharing Streamlining Initiative, developed by the TMA Privacy Board and approved in FY12, is both fortuitous and prophetic. The stand-up of the DHA and emerging changes within the MHS makes the Streamlining Initiative even more critical at this point, specifically related to not only increasing efficiency and enhancing compliance with HIPAA, but also enabling the consolidation of different types of regulatory reviews as an ultimate cost saving measure. FY13 was dedicated to laying the foundation for the Streamlining Initiative, including the development of uniform templates for HIPAA reviews within IRBs and/or HIPAA Privacy Boards, the development of a data determination guide in order to assist reviewers with properly categorizing the type of research related data requested for an appropriate compliance review, the creation and negotiation of the MOA setting forth the terms and conditions for delegating responsibility for HIPAA Privacy reviews of research projects, and an outline for training content required for IRB and HIPAA Privacy Board staff. The foundational work will be completed in early FY14, at which point the Streamlining Initiative will be deployed at WRNMMC, the first pilot site.

After completing the launch of the pilot project at WRNMMC, the DHA Privacy Board will continue the effort to delegate the authority for HIPAA compliance reviews to other MHS Multi-Service Sites with IRBs and/or HIPAA Privacy Boards capable of ensuring compliance with the HIPAA research provisions when a researcher requests PHI from MHS information systems. With the potential for backlog due to increases in data sharing requests related to research under the new DHA, the delegation of Privacy Board authority remains significant in enhancing efficiency by limiting the number of reviews conducted by the DHA Privacy Board and by allowing IRBs to combine the HIPAA Privacy Rule reviews with the required reviews of research protocols under the Common Rule.

As the Streamlining Initiative is deployed in its first pilot site at WRNMMC, the DHA Privacy Board will begin to develop its second role in the streamlining process, which involves developing an assessment program and compliance checks. To the extent possible, the assessment program will be integrated with site visits required by the Regulatory Oversight and Research Office, which are otherwise performed to measure compliance with the Common Rule. In FY14, the DHA Privacy Board will also update website

content to include new information about the Streamlining Initiative and to add a section on frequently asked questions and additional resources related to the initiative. The Board will continue to identify and implement necessary updates to the universal HIPAA compliant templates and data determination documents and ensure on-going training and dissemination of new and relevant information in the Streamlining Initiative. As the Streamlining Initiative is rolled out at WRNMMC, the DHA Privacy Board will also be working with other Multi-Service Sites in an effort to expand the initiative, and enhance the HIPAA compliance and effective HPAA reviews for research projects across the MHS.

Future Vision for the Privacy Board

To ensure compliance with the HIPAA Privacy Rule and DoD 6025.18-R and to bring quality service to our stakeholders, the DHA Privacy Office continually evaluates the legal and regulatory landscape, as well as Board processes and procedures, to make improvements, where necessary and appropriate. As part of these efforts, the Board continually assesses and strives for increased collaboration with the overall DHA Data Sharing Program, so as to improve the entire data sharing experience for researchers by making it as efficient and productive as possible.

This stakeholder-oriented focus is also apparent during Board meetings where the DHA Privacy Board considers areas where their expertise and experience may assist researchers in accessing data and, at the same time, ensuring compliance with laws that protect the privacy of the individuals whose data is accessed. In that regard, by adding the new current topic agenda item at DHA Privacy Board meetings, the Board hopes to explore other privacy and research related areas that might raise new ideas for future directions in protecting the privacy of DHA beneficiaries and serving researchers in their goal to use MHS data for their research studies.

Similar to the Board meeting focus on stakeholder input and collaboration, one of the most significant changes that occurred during FY13 was the work to implement the pilot project at WRNMMC for the Streamlining Initiative. Once the pilot is launched, the DHA Privacy Board will focus on developing the tools for the next phase which involves assessing the Multi-Service Sites to ensure compliance and expanding the Streamlining Initiative to other MHS Multi-Service Sites as well as continuous oversight, including revising and updating universal templates, procedures and processes as appropriate. In addition, the Board will ultimately provide online training to the Multi-Service site IRBs and continue to disseminate relevant information and resources.

Following the development of the TMA Privacy Board webpage during CY12, the webpage serves as a significant resource for informing the HIPAA and research community and for engaging in dialogue. As originally intended, the DHA Privacy Board hopes that the webpage will encourage and promote continual compliance with the HIPAA Privacy Rule research provisions and to build an open forum where ideas can be shared and topics relevant to the research community can be discussed.

Finally, the DHA Privacy Board will keep serving the research community by providing efficient HIPAA Privacy Rule reviews for researchers. As the Streamlining Initiative is rolled out, the Board will remain the reviewer for HIPAA compliance of researchers who work outside of the MHS Multi-Service markets, but who seek MHS data. Consistent with this purpose, the DHA Privacy Board will continue to meet in order to discuss the initial goals of assisting researchers to obtain reviews and documentation that are compliant with the HIPAA Privacy Rule.

Appendix A: DHA Privacy Board Members

HIPAA requires that a HIPAA Privacy Board: 1) has members of varying and appropriate professional competency; 2) includes at least one member who is not affiliated with the HIPAA covered entity (in this case MHS), not affiliated with any entity conducting or sponsoring the research, and not related to any person affiliated with any such entity; and 3) not have any member participating in a review for which the member has a conflict of interest. 45 CFR 164.512(i)(i)(B). Profiles of the current Board members follow:

• **Linda Thomas,** J.D., M.S., M.A., P.M.P., CIPP/G, Chief, DHA Privacy Office and DHA Privacy Board Chair

• **Rita DeShields,** B.A., DHA Data Sharing Compliance Officer, DHA Privacy Office and DHA Privacy Board Co-Chair

• **Jacob Bournazian,** J.D., M.A., Confidentiality Officer for the Energy Information Administration, Department of Energy

• **Dr. Kenneth Cox,** M.D., M.P.H., retired Colonel and civilian at the United States Army Public Health Command

• **CAPT John Eckert,** PhD, Program Manager, Human Research Protection Program, DoD/Office of the Assistant Secretary of Defense for Health Affairs/DHA Privacy Office

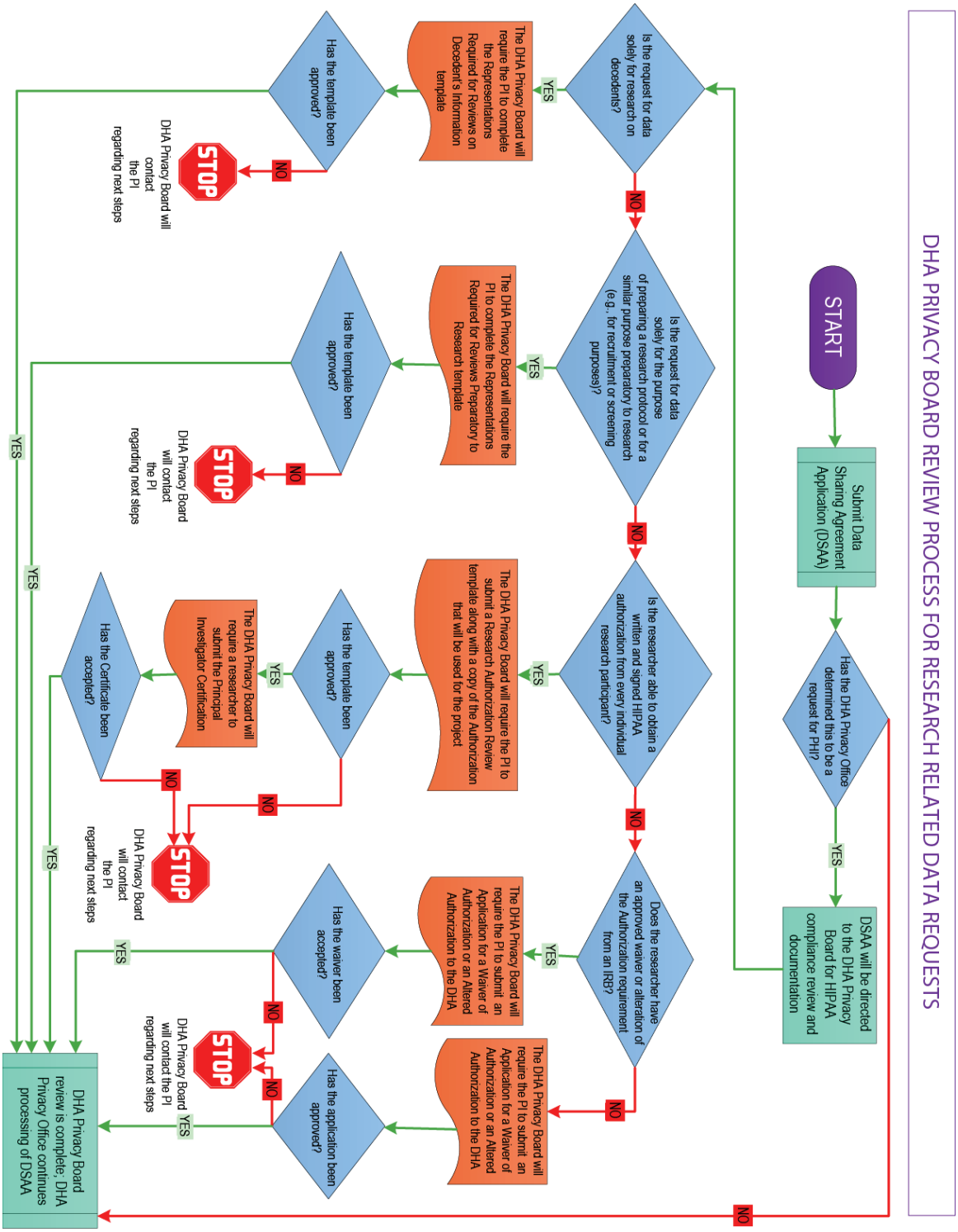
• **Eve Powell-Griner,** PhD, CIPP/G, Confidentiality Officer for the National Center for Health Statistics, Centers for Disease Control and Prevention

Appendix B: Centers/Institutions Served by the Privacy Board in FY13

Brooke Army Medical Center
Children's Hospital of Pennsylvania (CHOP)
DoD Pharmacoeconomic Center*
Defense and Veterans Brain Injury Center (DBVIC)
Infectious Disease Clinical Research Program* (NIAID)
Landstuhl Regional Medical Center (LRMC)
Naval Hospital Camp Lejeune
San Antonio Military Medical Center
U.S. Air Force School of Aerospace Medicine
U.S. Army Medical Research Materiel Command (USAMRMC)/Congressionally Directed Medical Research Programs (CDMRP)
U.S. Army Medical Command (MEDCOM)
U.S. Army Medical Department Center (AMEDD)
U.S. Army Telemedicine and Advanced Technology Research Center (TATRC)
U.S. Navy Bureau of Medicine and Surgery (BUMED)
Uniformed Services University of Health Sciences* (USUHS)
U.S. Army Institute of Surgical Research (USAISR)
William Beaumont Army Medical Center
Walter Reed National Medical Military Center* (WRNMMC)

*Represents the organizations referred to in the “Multi-Service” category on Figure 3, page 9

Appendix C: DHA Privacy Board Review Process for Research Related Data Requests Flowchart



Appendix D: The Federal Framework for the Protection of Human Subjects (also known as the "Common Rule") and the Health Insurance Portability and Accountability Act of 1996 (also known as the "Privacy Rule")

Researchers seeking to access and/or obtain the MHS data for research purposes must adhere to the separate and distinct requirements within *both* the Common Rule and the HIPAA Privacy Rule. In acknowledgment of the already established IRBs as the bodies for reviewing research under the Common Rule, the HIPAA Privacy Rule authorized IRBs and newly defined HIPAA Privacy Boards, such as the DHA Privacy Board, to conduct HIPAA Privacy Rule reviews. As a result, many misconceptions have arisen among IRBs and researchers regarding the type of review necessary for HIPAA compliance due to confusion between the Common Rule and the HIPAA Privacy Rule.

The chart and narrative below set forth the primary differences between the two applicable regulations. As indicated in the chart, although the Common Rule enables certain research projects to be exempt from IRB review, HIPAA Privacy Rule review and documentation is still required, even for exempt projects, before PHI can be used and/or disclosed. Furthermore, the requirements of informed consent are separate and distinct from those of a HIPAA Authorization. An informed consent can be joined with a HIPAA Authorization for research purposes, known as a "Compound Authorization" under the HIPAA Privacy Rule. HIPAA Authorizations or Compound Authorizations are required to be reviewed for compliance with the HIPAA Privacy Rule.

Differences Between the Common Rule and the HIPAA Privacy Rule

	The Common Rule	The HIPAA Privacy Rule
Federal Regulation	Protection of Human Subjects (45 CFR 46)	HIPAA Privacy Rule (45 CFR 160 and 164)
Department of Defense (DoD) Implementing Regulation	Protection of Human Subjects (32 CFR 219); Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (DoDI 3216.02)	DoD Health Information Privacy Regulation (DoD 6025.18-R)
Primary Purpose	Protect individuals who are the subject of research projects. Consideration is given to how various aspects of the research project, including privacy, confidentiality, data collection, data maintenance and data retention, impact physical, emotional, financial, and informational harms	Protect individuals against informational harm while allowing the necessary flow of health information with specific rules pertaining to the privacy and security of PHI
Threshold Requirement	Informed consent from each research participant (oral and/or written)	HIPAA Authorization from each research participant *(must be written and signed)*
Enforcement	Office for Human Research Protections, United States Department of Health and Human Service (HHS), and DoD Assistant Secretary of Defense for Research and Engineering	Office for Civil Rights, HHS
Administration	IRBs	IRBs or HIPAA Privacy Boards
Exemptions	Human Research Protection Officials (HRPOs) and/or IRBs can exempt certain research projects from IRB review in accordance with 32 CFR 219.101(b)	None. All research projects seeking PHI from a HIPAA covered entity, including Defense Health Agency (DHA), must comply with the HIPAA Privacy Rule

Appendix E: Glossary

AHLTA	Armed Forces Health Longitudinal Technology Application
BAA	Business Associate Agreement
CY	Calendar Year
CDC	Centers for Disease Control and Prevention
CHCS	Composite Health Care System
CIPP/G	Certified International Privacy Professional/ Government
DHA	Defense Health Agency
DHA Privacy Board	Defense Health Agency Privacy and Civil Liberties Office Privacy Board
DHA Privacy Office	Defense Health Agency Privacy and Civil Liberties Office (formerly known as the TMA Privacy Office)
DHP	Defense Health Program
DHHS	Department of Health and Human Services
DHSS	Defense Health Services Systems
DoD	Department of Defense
DoDI	Department of Defense Instruction
DSA	Data Sharing Agreement
DSAA	Data Sharing Agreement Application
EPA	Environmental Protection Agency
FOIA	Freedom of Information Act
FY	Fiscal Year
GINA	Genetic Information and Non-Discrimination Act
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIPSCC	Health Information Privacy and Security Compliance Committee

HITECH	Health Information Technology for Economic and Clinical Health
HRPP	Human Research Protection Program
IRB	Institutional Review Board
MHS	Military Health System
MOA	Memorandum of Agreement
MTF	Military Treatment Facility
NCHS	National Center for Health Statistics
NoPP	Notice of Privacy Practices
OCR	Office of Civil Rights
OGC	Office of General Counsel
PHI	Protected Health Information
PI	Principal Investigator
PII	Personally Identifiable Information
PMP	Project Management Professional
SOP	Standard Operating Procedure
Sponsor	Government Sponsor
TMA	TRICARE Management Activity
TMA Privacy Board	TRICARE Management Activity Privacy and Civil Liberties Privacy Board
TMA Privacy Office	TMA Privacy and Civil Liberties Office (Succeeded by the DHA Privacy and Civil Liberties Office)
VLER	Virtual Lifetime Electronic Record
WRNMMC	Walter Reed National Military Medical Center